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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,609	10/09/2001	Shlomo Gabbay	SHEP5010US	8158
26294	7590	08/01/2006	EXAMINER	
TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 1300 EAST NINTH STREET, SUITE 1700 CLEVEVLAND, OH 44114			PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 08/01/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/973,609	<b>Applicant(s)</b> GABBAY, SHLOMO	
	<b>Examiner</b> Brian E Pellegrino	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2006.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21-28, 51, 52 and 61-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-28, 51, 52 and 61-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_      6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 5/10/06 has been entered.

### ***Response to Amendment***

The following Office Action contains rejections to previously objected-to-as-allowable material as indicated in Office Action mailed 4/27/04. It is noted amendments were made to claims 21,22,27,28,51 and new claims 61-70 added. Accordingly, the following action has been made Non-Final.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

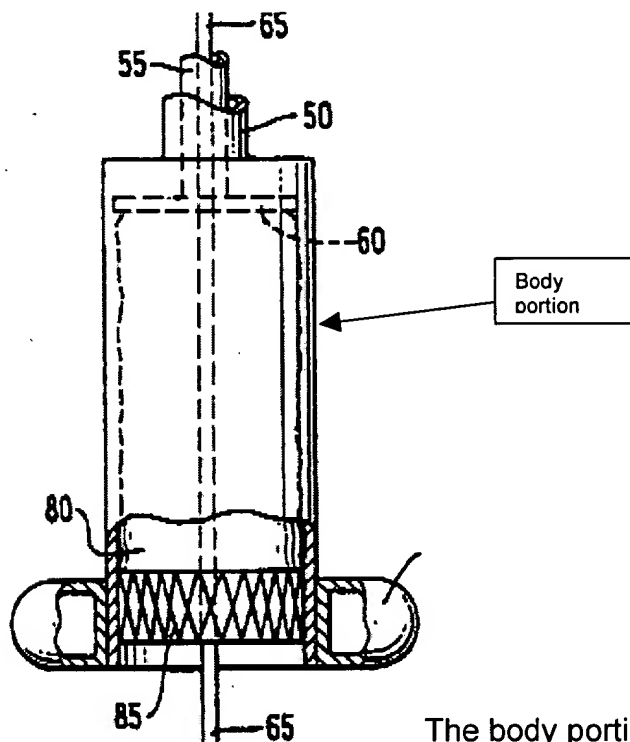
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21,51,61-63,67,70 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens (5370685). Fig. 9 shows an implantation system with an

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elongate cylindrical member **50** with an inner diameter that falls within the claimed range of 5-15mm, col. 7, lines 65,66. It can also be seen there is a body portion as seen below.



The body portion and cylindrical member being

coaxial and the body portion having a greater diameter than the cylindrical member. It can also be seen mounted within the system is a heart valve prosthesis with a generally cylindrical support **85** having a valve fixed between the ends of the support. Fig. 10 illustrates the system includes a plunger **60** to urge the prosthesis from the cylindrical member. Stevens discloses the valve can be natural tissue heart valve, col. 9, lines 7-13. Stevens also discloses the support structure can be made of shape memory like material, col. 9, lines 23-29. Figs. 11 & 12 show projections **90** biased to extend radially from the support.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens '685 in view of Torossian (5851210). Stevens is explained supra. However, Stevens fails to disclose indicia on the cylindrical member. Torossian teaches (Fig. 2) indicia **54** are placed on the cylindrical member or catheter. Torossian additionally teaches the indicia are used to facilitate implantation of the device, col. 6, lines 26-28. It would have been obvious to one of ordinary skill in the art to incorporate indicia on the cylindrical member as taught by Torossian with the implantation system of Stevens such that it enables the surgeon to accurately place the valve in the location desired and know when it is at the implantation site by the use of the indicia.

Claims 22-26,65,66,68,69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens '685 in view of Shokoohi et al. (6077296). Stevens is explained above. However, Stevens fails to disclose the support structure including biasing elements. Shokoohi et al. teaches (Fig. 2) an expandable prosthesis with a plurality of support features **54** joined by connecting element **56**. It can also be seen at the proximal and distal ends **55,59** that the projections extend radially outward and are triangular. Shokoohi also teaches that suture can be used to limit the outward expansion, col. 7, lines 32-39. Shokoohi also shows (Fig. 11) that the support features can have springs **60** at the ends for receiving the suture so sections attached will not separate. It would have been obvious to one of ordinary skill in the art to incorporate

biasing elements as taught by Shokoohi with the prosthesis of Stevens such that it has enhanced securing means to hold a longer prosthesis together.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens '685 in view of Vesely et al. (5549665). Stevens is explained supra. However, Stevens fails to disclose the use of a sheath to cover the exposed parts of the support. Vesely et al. teach to cover the exposed parts of the stent support (Figs. 2,4) using a sheath or covering 35. It would have been obvious to one of ordinary skill in the art to use a sheath as taught by Vesely with the prosthesis of Stevens such that the stent support is covered to provide a smooth surface so no rigid structure can cause trauma to the surrounding tissue. Additionally, the sheath would prevent contact of the metal support with surrounding tissue and eliminate any possibility of irritation or allergic reaction to metal.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens '685. Stevens is explained as before. However, Stevens fails to disclose the use of a pulmonic valve. It would have been an obvious matter of design choice to modify the type of valve used, since applicant has not disclosed that using a pulmonic valve provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the type of valve chosen as taught by Stevens such that it corresponds to the one being replaced or the claimed pulmonic valve in claim(s) 28 because both heart valve prostheses perform the same function of being

restrained in a first condition in a delivery device and then expanded into a second condition when implanted and provides a functioning valve replacement.

Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens '685 in view of Del Toro (5733267). Stevens is explained above. However, Stevens does not disclose a handle portion attached to the body of a cylindrical member for delivering the prosthesis. Del Toro teaches (Fig. 4) a handle **40** attached to the body of a cylindrical delivery device **32**. It would have been obvious to one of ordinary skill in the art to use a handle as taught by Del Toro with the delivery device of Stevens such that the surgeon can accomplish accurate control of the delivery device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).